PILOT®
DIODE LASER

OPERATOR'S MANUAL

FASTER HEALING. BETTER RESULTS.

CAO GROUP, INC.
Easier · Faster · Better™

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SECTION 1 – INTRODUCTION

CAO Group has developed the Pilot Diode Laser, the most practical infrared laser technology available for performing therapeutic procedures. The laser energy provided by the Pilot Diode Laser is shown to reduce healing time and increase blood circulation within the treated sites. The laser's energy is delivered through a 400 micron silica filament to the reusable handpiece. The Pilot Diode Laser increases blood circulation to muscles, joints and other areas of the body to allow patients to heal safely and more quickly with less pain, inflammation and infection. Weighing 5.5 pounds, the Pilot Diode Laser is controlled by a wireless foot switch that offers maximum flexibility in unit positioning.

FEATURES

- 810nm wavelength for rehabilitation
- Up to 9.0 Watt laser output
- Easy exchange of the ergonomic handpiece to reduce cycle time, increase patient throughput
- Sterilizable handpiece sleeve
- 630nm aiming beam for illumination of working site
- Easy to operate intuitive program
- Compact size and light weight

The major components of the Pilot Diode Laser are semiconductor "chips" that are commonly referred to as AlGaAs. They are activated or "pumped" by passing an electrical current through the diode to produce an elliptical shaped display of monochromatic light that can be focused into a very small point and placed into the delivery fiber. Pilot Diode Laser generates energy in two wavelengths, 810nm and 630nm. The energy produced at 810nm is used for rehabilitation; it is invisible non-ionizing radiation that does not create changes in cellular DNA. The energy produced at 630nm illuminates the site.

SAFETY

Laser safety is of paramount importance and each office should quickly develop and implement a laser safety program and identify a "Laser Safety Officer" (LSO) to be responsible for the laser. The LSO's duties include management of the laser and all accessories as well as training office personnel in all aspects of laser safety.

ALWAYS test fire the laser away from tissue before using it on a patient. The doctor, staff, patient and anyone present in the operatory should be wearing the appropriate safety eyewear whenever the laser is being operated. Strict adherence to protocols for safe laser use is essential.

SECTION 2 – SPECIFICATIONS

2.0 Laser Specifications

Weight	5.5 lbs
Dimensions in Inches (H x W x L)	5.5" x 6.25" x 8.75"
Laser Classification: (Per IEC 60825)	
Laser Diode	Class 4 Laser Device
Wavelength:	
Laser	810nm ± 20nm
Aiming Beam	630nm – 660nm ±15nm
Beam Divergence	13 degrees ± 1 degree
Power Range	100 mW to 9 Watts
Hertz Rate in Pulsed Mode - Fixed	10.0 Hz
Pulse Duration - Fixed	0.05 seconds
Duty Cycle	
Pulsed Mode	50%
Continuous Wave	100%
Aiming Beam (3 mW)	Yes
Audible Notification	Yes
Visual Notification	Yes
Power Requirements	110 – 120 VAC @ 60 Hertz 220 – 240 VAC @ 50 Hertz
Amperage	1.5 Amps @ 110 – 115 VAC 0.75 Amps @ 210 -230 VAC
Cordless Foot Pedal:	
Frequency	2.4 GHz
Battery	9 volt Lithium
Operating Temp	20ºC - 30ºC (68ºF - 86ºF)
Storage Temp	-20ºC - +40ºC (-5ºF - +105ºF)

2.1 Delivery System Specifications

2.1.1 Quartz Silica Fiber

Fixed Cable Length (6 ft)	
Delivery Fiber Diameter	400 microns
Autoclavable	No

2.1.2 Handpiece Sleeve

Autoclavable	Yes

SECTION 3 – LASER ASSEMBLY AND SETUP

3.0 – Instructions on Unpacking and Dealer Assistance

Do not attempt to unpack the laser and install the various components without reading the manual first. If you are unsure about any aspect of the assembly, call your authorized dealer.

3.0.1 – Shipping Container Information

Please keep the shipping box. If you need to return the laser, repack it in the original box.

3.0.2 – Contents of Shipping Container

1) Pilot Diode Laser Unit with 400 Micron Fiber with 6' cord for handpieces
2) Autoclavable Therapeutic Handpiece Sleeve
3) Protective Laser Goggles
1) Laser Key
1) Wireless Foot Pedal
1) 9 Volt Lithium Battery
1) Power Cord, Hospital Grade, 8' long
1) Pilot Diode Laser Owner's Manual
1) Laser Safety Sign

3.0.3 Power Cord Installation *(see Figure 3.0 on page 8)*

- Remove the power cord from the Pilot Diode Laser package.
- Plug the power cord into the appropriate receptacle on the back of the laser.
- To prevent power surges due to electrical storms or spikes in line voltage, use a power strip with a circuit breaker or unplug the laser when you are not present.
- Plug the power cord into a 110 Volt AC outlet rated at 60Hz.

3.0.4 Power/Fan Switch *(see Figure 3.0 on page 8)*

- The power/fan switch for the laser and fan is the first item you turn on.
- The switch is located on the rear panel of the laser near the lower left hand corner.

3.0.5 Laser Key Switch *(see Figure 3.1 and 3.1a on page 8)*

The laser key switch is the main safety switch for your laser.

- Place the laser key into the key receptacle located near the lower right corner on the front of the laser.
- Check the key switch by turning the key clockwise approximately 1/4 of a turn. This is the (ON) operating position for the key.
- The fan will start when the power/fan switch is on and the key is turned.
- Prior to leaving the office check to see that the key switch has been turned off and the key removed and stored in a safe place.

3.0.6 Remote Interlock

The Pilot Diode Laser is equipped with a Remote Interlock Jack. The Remote Interlock Jack is provided so that a clinician may install the laser in a dedicated laser treatment room such that the laser will be interlocked with the entrance door of the room. In such an interlocked installation, the laser would shut off anytime the door is opened to protect the eyes of the person who is entering the room. It is recognized that this method of installment is not facilitated or practical in many operatories or clinics. The Remote Interlock Jack is available to any practitioner that requires it. The Remote Interlock Jack is located and clearly labeled on the rear of the laser. The mini phono jack is wired in the normally closed position; meaning that no further action is required to operate the laser without the interlock loop. If the interlock loop is desired you may purchase the loop from CAO Group, Inc. You need only to contact CAO Group Customer Support and let them know that you require a mini (1/8") mono-phono jack wired into a normally closed momentary switch and select the switch design that best suits your needs. To install the loop, install the switch on the door and simply plug the mini phono jack into the Remote Interlock Jack on the rear of the laser.

3.0.7 Foot Pedal Battery Installation Instructions

The 9 Volt Lithium battery and battery cover will need to be installed before the Pilot Diode Laser will function.

3.0.8 Emergency Shutdown Switch *(see Figure 3.4 and 3.5 on page 9)*

If the shutdown switch is locked down, the laser will not turn on. Before you can activate the laser, you must first check to see if the emergency shutdown switch has been depressed prior to shipment and locked in the off position.

- The switch is the red button located on the top of the laser.
- Release the switch by grasping it between your thumb and index finger, and gently depress it as you turn the button 1/4 turn clockwise.
- You will feel it "click" or release and the spring loaded button will pop back up
- The display on the control panel should now be lighted.
- If the laser can not be activated, please contact the manufacturer. (See page 24 for contact information.)

1. Make sure the laser is completely turned off before placing the battery in the foot pedal.

2. Place the pedal face down on a hard, clean surface. (Figure 1)

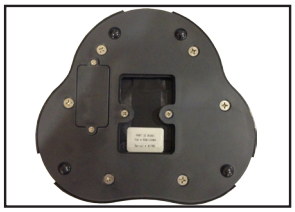


Figure 1

3. Insert a Phillips head screwdriver into the screw holding down the battery cover. Rotate the screwdriver counterclockwise until the screw comes out completely. Repeat for the other screw holding down the battery cover. (Figure 3)

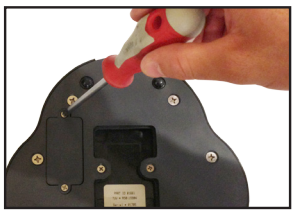


Figure 3

4. Push down on one end of the battery cover while simultaneously lifting up on the other end to remove the battery cover. (Figure 4)

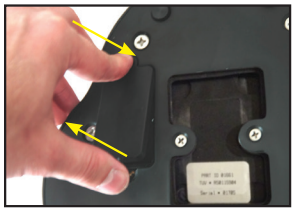


Figure 4

5. Locate the battery terminal inside the well. Do not pull excessively on the wires.
Note: Touching the terminals incorrectly with the battery can damage the wireless chip. (Figure 5)

Figure 5

6. Remove the battery from its packaging and attach the battery to the terminal. (Figure 6)

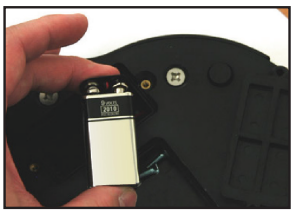


Figure 6

7. Place the battery in the well with the connector to the same side as the wire leads emerge from the housing. (Figure 7)

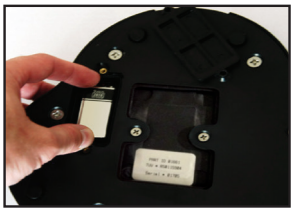


Figure 7

8. Replace the battery cover.

9. Replace the screws. Turn the screwdriver clockwise to tighten the screws. The screws are sufficiently secure once they no longer turn with gentle force. **DO NOT OVER TIGHTEN.** (Figure 8)

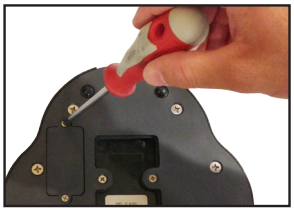


Figure 8

NOTE: It is recommended only to use a 9 Volt Lithium battery to power the cordless foot pedal. This type of battery has been tested to last for over 100 hours of foot pedal operation. When the battery voltage begins to drop, the foot pedal will begin to beep, signaling that you have approximately 2 hours of operating time left before the battery life is completed.

NOTE: A 9 volt alkaline battery may be used; however the life expectancy of an alkaline battery is less than 35 hours of operating time.

3.0.9 Summary: Laser Assembly Instructions

1. Attach the laser's power cord and place the plug into the wall receptacle.
2. Install the foot pedal battery.
3. Pair the foot pedal to main unit – see Channel Programming Procedure.
4. Attach remote interlock, if desired.
5. Check the emergency shutdown switch to see that is has been released.
6. Remove dust cap from end of handpiece stem.
7. Attach the preferred therapeutic handpiece.
8. Place the key into the key switch receptacle (Figure 3.1a) and turn the key to the right. The console should light up.
9 The light on the console indicating the operating status should be in the standby mode.

NOTE: When the power cord is plugged in, the fan/power motor switched on, the wireless foot pedal receiver programmed and the emergency shutdown released, the key will turn the laser on.

3.0.10 Visual Assembly Aides

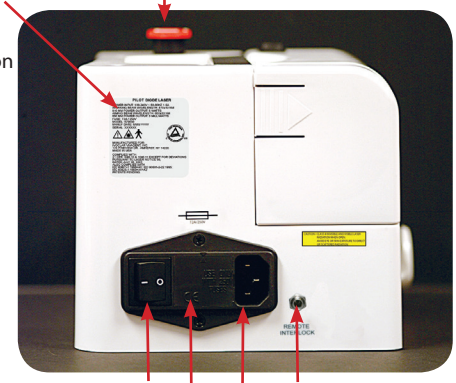


Figure 3.0

PILOT Diode Laser Digital Display

LED Screen

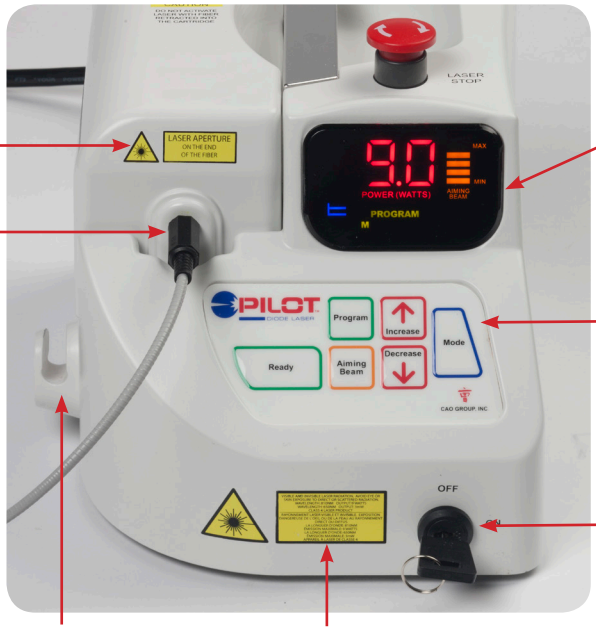


Figure 3.1

Figure 3.1a

Turn the key 1/4 of a turn to the right to turn on the laser

Figure 3.2 - Control Pad Settings

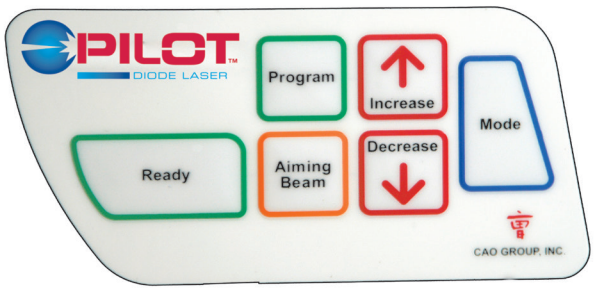
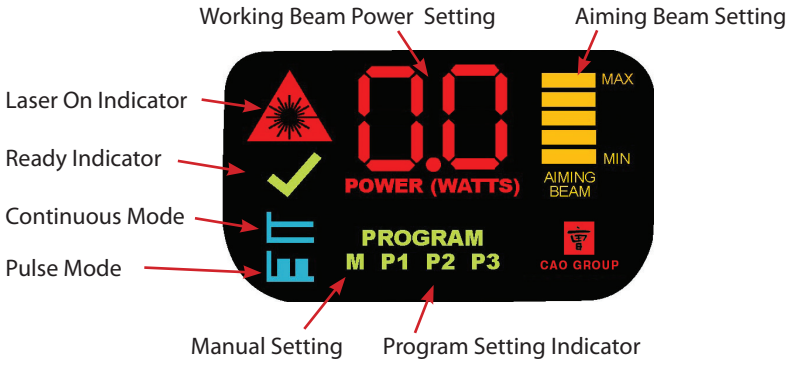


Figure 3.2a - Display Indicators



Mode: Press this key to select Continuous or Pulse mode.
Aiming Beam: Use these to adjust the aiming beam power.

Program: Press this key to select either manual (M) or one of three user defined programs (P1, P2, P3). Each program will save the parameters – working beam, aiming beam and mode of operation.

The settings can be changed as desired for any of the program modes. To set the user defined program modes, choose P1, P2 or P3, set your preferred settings and push the ready button. Upon activating the ready button, the new settings will be retained.

Increase and Decrease: Use these to adjust the power setting from 0 to 9 watts. Hold the desired key to rapidly change the value.

Figure 3.3 - Wireless Foot Switch

Laser On: This illuminates when the foot pedal is depressed, this indicates that the working beam (810 nm) energy is being emitted.

Ready Indicator: This illuminates when the READY key is pressed. It will blink for 3 seconds, and then remain steady. Once it's continuously lit, the aiming beam will be activated.

Continuous and Pulse Mode: This illuminates when the unit is in continuous mode. Use the MODE key to toggle back and forth between Continuous and Pulse.

Working Beam Setting: Indicates the working beam power output setting.

Adjustable Aiming Beam: The Pilot Diode Laser is actually two lasers in one, the infrared 810 nanometers wavelength laser which performs the actual treatment of the soft tissue and the 630 nanometers "laser pointer" which illuminates the direction where the laser will be used. Each bar represents 20% of maximum intensity. Thus 0 bars means the aiming beam is shut off.

Program Setting Indicator: Shows the current program mode that is selected. Pressing the PROGRAM button will cycle through the programs left to right, then back to manual "M".

Check The Emergency Shutdown System

1. Depress the red button on the top of the system until you feel it click into the shutdown (OFF) position.

2. Depress slightly and turn right ¼ of a turn to release. The emergency stop will pop up and the LED screen will light.

Figure 3.4 Shutdown

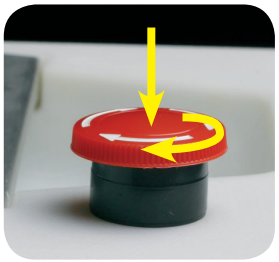


Figure 3.5 Release

3.1 Evaluating The Facility and Environmental Considerations (United States)

In order to insure the safe use of the laser in your facility, please check to make sure that the proposed location has the following:

- **3.1.1 Power Requirements**
  - 100 – 240 VAC±10 %
  - 3 Amps
  - Frequency range 45-63 Hz
  - 9 volt Lithium battery
- **3.1.2 Heating and Ventilation**
  The room where the laser is used should have good cooling and heating system so that the laser can be operated within the optimum range of 20° - 30°C (68° - 86°F). Avoid storing or transporting the laser in temperatures below -20° Celsius (-5°F).
- **3.1.3 Lighting**
  Overhead lighting should provide enough illumination to see properly, accessory lighting devices may also be used.

- **3.1.4 Combustible Chemical and Gases**

  All liquids and gases that are combustible or support combustion and are used in the treatment area where the laser is in use must be turned off during the procedure. Cleaning supplies or other flammable chemical compounds should be stored in an area away from the treatment area in order to avoid possible combustion.

- **3.1.5 Access and Visual**

  Access to the treatment area should allow the team to restrict entry while the laser is in use. There should be a Laser In Use Safety Sign placed in a designated area adjacent to the entry into the treatment area. (See Figure 7.1)

- **3.1.6 Channel Programming Procedure**

  There is no concern if 2 or more Pilot Diode Lasers in the same office or area are set to the same channel. Each laser and its corresponding pedal have additional programming that is unique to the pair. The pedal from one laser will not activate any other laser. However, if units on the same channel are near each other, the transmissions from one may interfere with the signal from another and thus prevent the second laser system from operating properly. It may become necessary to change the channels on one or more units to minimize interference.

Channel Programming Procedure

1. Make sure the unit is off before going forward with the programming procedure. Do not press the foot pedal for at least 30 seconds before proceeding.

2. Before turning the unit on. Press and hold PROGRAM.

3. While holding the program key down, turn on the unit, the display will briefly show "=P", then show "c1" for channel 1, "c2" for channel 2, up to channel 8 (depending on what programmed channel the unit is already on). Release the PROGRAM key.

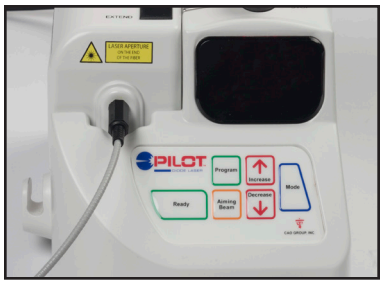
4. Press the INCREASE key to scroll up through the channels, from 1 to 8. Press the DECREASE button to scroll from 8 back to 1 to select the desired channel.

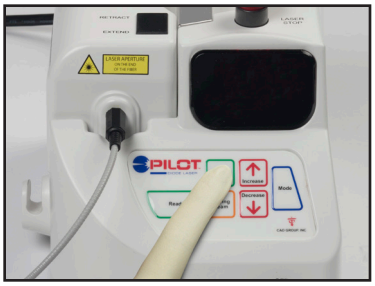
5. Once the desired channel is selected, press PROGRAM again. The unit will beep the same number of times as the channel selected. After a few moments the display will show "- - ".

6. With the main unit in this condition " - -", press the pedal. While the pedal is pressed, the display will change to "-I I-". The pedal is now set to the same channel and is matched with this laser. When the pedal is released, the display will return to "- -". This indicates that the channel change was successful and the new channel is saved in the memory.

7. If any problems occur during this process, the display will show "E r". If this occurs, turn the unit off, then on again. The original channel should be restored.

8. Once channel programming is complete, turn the unit back power fan switch off, then on again. The laser display should return to a laser power setting.


Step 1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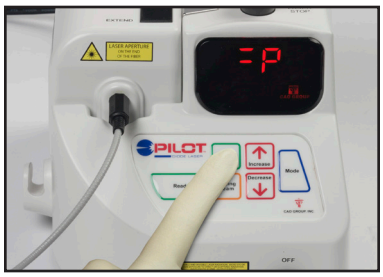
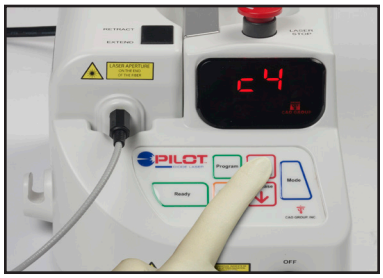


Step 3

Step 3 (continued)



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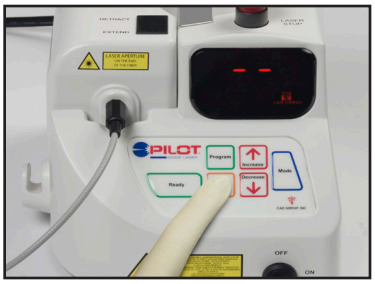
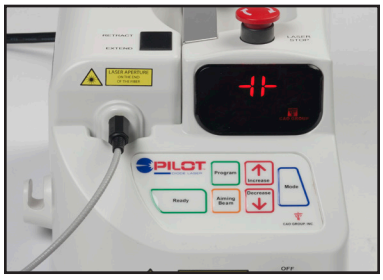


Step 5



Step 6

3.1.7 Pilot Diode Laser Frequency:

The 2.4GHz frequency is popular for networks and other wireless devices that share similar technology. The nature of spread-spectrum modulation in the 2.4GHz frequency means that a multitude of devices can co-exist in the same 2.4GHz spectrum. Since the Pilot Diode Laser 2.4GHz wireless receivers have a much lower power output, it is unlikely that they would "interfere" with higher-power devices. If this were to occur, the higher-power devices would quickly switch to another channel to achieve uninterrupted operation.

The 2.4GHz wireless receiver uses an entirely different modulation scheme, and can not de-modulate (receive) data from Wi-Fi of Bluetooth devices. The converse is also true; their modulation methods are incompatible.

Pilot Diode Laser is electronically coded: each pedal and Pilot Diode Laser share a **UNIQUE SERIAL NUMBER INTERLOCK** protocol for reliable operation:

- The pedal communicates with only one Pilot Diode Laser, there is a 2-way electronic code which must be verified for easy transmission and acknowledgement. The pedal and laser unit are interlocked to only each other's electronic codes.
- If data from any other pedal is ever received by the Pilot Diode Laser, embedded verification measures ensure that it is always ignored and discarded.
- If data were ever received from another wireless device with a compatible modulation scheme (2.4GHz frequency), it would immediately be discarded in the same way.

In summary, the wireless receivers in the Pilot Diode Laser have less than 2% of the output power of typical Bluetooth or Wi-Fi devices, and therefore can not mistakenly receive data from such devices.

SECTION 4– SAFETY CONSIDERATIONS

The safe use of the Pilot Diode Laser is the responsibility of the entire team including the doctor, staff and Laser Safety Officer. Protocols for the safe use of lasers have been developed by a combination of medical professionals working in concert with educators at the university level, scientists and laser manufacturers. Sound judgment and the concern for patient safety should be the basis of all laser care. The following entities have influence over laser use.

4.0 Food and Drug Administration

Manufacturers of products subject to performance standards under the Federal Food, Drug and Cosmetic Act, Chapter V, Subchapter C – Electronic Product Radiation Control are required to certify compliance with the regulations and furnish various reports to the Center for Devices and Radiological Health (CDRH). For medical laser manufacturers, additional review by the FDA of the safety and effectiveness of the device is required. Companies who intend to market a medical laser today must receive authorization from the FDA to permit the device into commercial distribution. There are two forms of pre-market clearance procedures. The premarket notification (510(k)) procedure is principally used for those devices that are documented to be substantially equivalent to legally market Class I and Class II devices. For new devices not equivalent to legally marketed devices, a more complex PMA is required.

4.1 Wireless Technology

In order to promote efficient use of the radio spectrum in various global markets, the US FCC (Federal Communications Commission) and other international government agencies have developed technical standards for devices that are capable of emitting radio frequency energy when in use such as wireless data cards. These products need to receive certain identification numbers in accordance with the Commission Equipment Authorization rules prior to marketing in US markets. The Code of Federal Regulations, Title 47 (47 CFR), Part 15 covers the rules for the operation of unintentional, intentional or incidental radiators. Any electrical or electronic devices incorporating a digital circuitry and operating with an oscillator or clock speed of greater than 9kHz requires approval to this rule. There are various types of FCC Part 15 approvals, depending on the nature of the product and its intended use. In Canada, IC –RSS 210 (Radio Standards Specification) sets out the requirements for license exempt low-power international radiators. This standard is very closely harmonized in terms of permitted frequencies, types of operation, and other technical requirements to the FCC requirements, but a separate certification application is required for Canada. In the European Community, compliance with several safety directives and testing to EN 300 328, EN 60950 and EN 301 489 is required for this type of device. The manufacturer is required to provide a Declaration of Conformity as evidence of its compliance with the various regulatory requirements.

4.2 Statutory Licensure

Check with your state certification board to confirm requirements for licensure and use of the Pilot Diode Laser.

4.3 OSHA and its Provisions

Worker safety is the responsibility of the employer and is regulated by OSHA (Occupational Safety and Health Administration), a division of the U.S. Department of Labor. OSHA has issued no specific standard for safe use of lasers but recognizes ANSI standard Z136.1 as a source for analyzing safety with respect to medical lasers. For more information see OSHA Technical Manual (TED 1-0.15A) Section III, Chapter 6, 1999. CAO Group recommends implementation of a Laser Safety Program for the safety of you patients and office staff in connection with the use of the Pilot Diode Laser.

4.4 Laser Safety Program

CAO Group recommends implementation of a Laser Safety Program appropriate for your office. The plan should include the following:

- Delegation of authority and responsibility for supervision and control of the laser to a designated Laser Safety Officer.
- Minimum training requirements for users of lasers.
- Security preventing unauthorized use of the laser.
- Standard operating procedures to regulate the work environment in order to protect the patient and office staff from laser hazards.

The safe use of a laser is the responsibility of the Laser Safety Officer (LSO). It is their responsibility to train the staff, maintain records concerning training, the laser's performance, perform safety checks and prepare the laser for use on a daily basis. The LSO must keep records of any incidents that relate to the failure of the laser or any adverse effects related to laser therapy and report such incidents as prescribed by law. The LSO assures that a medical follow-up has been sought or has occurred following any adverse incident during treatment. The LSO is responsible for the training of all office personnel who are involved with the laser preparation and use. Daily checks of the facility and equipment are also the LSO's responsibility. The LSO should test fire the laser each day prior to beginning each treatment procedure. For more information on the contents of a Laser Safety Plan you can review ANSI Standard Z136.3 for Safe User of Laser in Health Care Facilities or IEC 60825-8 Guidelines for the Safe Use of Medical Laser Equipment.

4.5 Continuing Education

The Laser Safety Officer should insure that the operator and staff attend laser courses taught by qualified laser educators. Ongoing reviews of laser safety procedures should be a part of normal office routine.

4.6 In-Office Safety Issues

4.6.1 Lighting

Always use the Pilot Diode Laser in a well lit and ventilated area.

4.6.2 Safety Eyewear

While using the Pilot Diode Laser, doctors, auxiliary staff, patients and anyone attending them in the treatment area must wear the appropriate safety eyewear that has been designed for the use with the 810nm wavelength. Never point the laser tip directly at the face, eyes or skin of anyone while emitting energy. The aiming beam is also capable of causing eye damage.

4.6.3 Test Firing the Laser

For therapeutic uses, it is not necessary to test-fire the Pilot Diode Laser prior to using it.

4.6.4 Danger - Laser in Use Signage

Each area where a Pilot Diode Laser is used should have a "Laser In Use" sign placed at the entrance when a procedure is in progress, this will help eliminate eye damage caused by inadvertent exposure to laser energy.

4.6.5 Dust Cap Removal

Prior to using the 9W Pilot Diode Laser, first you must remove the dust cap that protects the fiber. To remove, just pull the dust cap out from the end of the handpiece stem. If this is not removed prior to firing the laser, you risk damaging the unit. The dust cap should be replaced when the laser is not in use or being stored.

4.6.6 Sponge Removal
All sponges used for cleanup of lasers should be disposed of in a biohazard bag for contaminated soft products.

4.6.7 Key Switch and Mode Selection
When the key switch is in the ON position (turn to the right), the laser has been enabled and can be activated while in the READY status. When not in use, insure the key has been turned off or that the laser is placed in the STANDBY status.

4.6.8 Safety Education
Provide comprehensive safety procedure training for all office personnel and include the staff in all outside laser courses when possible. Be certain that all members of the team understand how the laser works.

4.6.9 Laser Security
To prevent the unauthorized use of the laser while not in use, the key should be removed from the unit and maintained by the Laser Safety Officer.

4.6.10 Emergency Shutdown Options
Any of these mechanisms can be used to shut down the emission of the laser energy in a real or perceived emergency.

1. Depress the emergency shutdown button
2. Foot Pedal - Remove your foot to stop lasing
3. Key – Turn off the key
4. Switch the Power/Fan to the off position (O)
5. Power Cord – Unplug from the wall outlet

4.7 American National Standards Institute (ANSI) – Safety Standards
ANSI is a non-governmental, non–profit agency that has established guidelines and safety standards for the use of lasers and other electro-optics. ANSI establishes guidelines for safety eyewear and classifies all lasers based on their potential for damage to eyes or tissue. You will also find information concerning lasers at Lasermet.com.

SECTION 5 – OPERATING THE LASER
The Pilot Diode Laser will deliver energy in either a continuous wave (CW) mode or in a pulsed mode which are called temporal emission modes (time related modes). Selecting the appropriate mode is a factor in controlling target tissue temperatures and the efficiency of energy delivered. The pulse duration (.05 seconds) and the number of pulses per second (10) have been fixed by the manufacturer using a 50% duty cycle and you will therefore need only to change the power and mode settings.

5.0 Standby and Ready Status
Once you have turned on the power/fan switch on the back of the laser and the key switch on the front, you will see the laser's LED screen light up. The status of the laser will be in "Standby", which is a non-active status. The laser will not emit energy while in "Standby", even if you depress the foot pedal. Press the READY button to place the unit in the ready status. When this button is pressed, whatever settings are displayed on the unit will be saved into the unit's memory for the program setting shown. The settings saved into the three programmable modes will be retained even if the laser is turned off. Any adjustments to the manual settings after the laser is in the ready status will not be saved to memory. The laser will now be ready to emit energy as you depress the foot pedal.

5.1 Continuous Wave (CW) Mode *(see Figure 3.2 and 3.2a)*
The Continuous Wave (CW) mode, will deliver the amount of energy in joules in one second that you have set the laser for (i.e., set the laser for 2 Watts CW and while in the ready mode, the laser will deliver 2 joules of energy per second as long as you have the foot pedal depressed.).

5.2 Pulsed Energy Mode
Pulsing the laser will allow some cooling of the tissue in between emissions of energy. The "duty cycle" is the percentage of the time in each second that the laser is emitting energy. The pulses per second, the duty cycle and the energy intensity per pulse will determine your average power. In the pulse mode the Pilot Diode Laser is programmed to deliver 10.0 pulse per second with each pulse lasting for 0.05 seconds. The duty cycle is set for 50%, so you will have 1 energy pulse with 1 periods of rest with no energy between each pulse. If the laser is producing energy at 10 times per second for 0.05 seconds per pulse, you will be producing energy for a total of 0.5 seconds for every 1 second the laser is active. The result will be an average power per second that will be 50% of what you have set the laser for. When using pulsed energy, you will have to adjust your power upward in order to achieve the same rate of work as the same power set in CW. 2 Watts of Pulsed energy will be the same average power output as 1 Watt CW.

5.3 Tissue Responses to Laser Energy
Maximum results will be achieved by regulating the power and the speed that the operator moves the handpiece over the targeted tissue. It is possible to induce an adverse inflammation response equivalent to a first-degree sunburn if too much power is used and/or handpiece is kept stationary over the same tissue for too long. Always use the least amount of power necessary to complete your procedure. Several factors should be considered for a laser treatment: the patient's age and skin type, localized pigmentation (ex. moles, liver spots), the desired treatment effect, the area of the body being treated, the laser power and mode settings, the handpeice size, and the speed at which the handpiece is moved.

Selecting the appropriate settings creates a beneficial effect that helps increase the amount of blood flow circulating to a muscle, joint, or area of the body experiencing low circulation. This can be used to treat cases of muscle and joint pain. Simply attach the therapeutic handpiece onto the end of the fiber cable. With the desired setting selected, move the handpiece over the muscle, joint, or area in smooth, circular motions. Do this until desired length of time has been reached. When completed, the handpiece should be autoclaved.

The handpiece system is designed such that the handpiece should be placed in direct contact with the patient's tissues. Only light pressure is needed to keep the handpiece in contact with the tissue - it is uneccessary to forecefully knead the handpiece into the patient's tissues.

5.4 Fiber and Handpiece Care
The handpiece should be autoclaved after each patient. Take care to avoid bending the fiber cable in a tight circle or subjecting it to blunt force as these may cause the fiber to crack or break. Radiation exposure may occur in these instances which could be harmful to yourself, your staff and your patient. Special care should be taken not to kink or crush the fiber cable. As the aiming beam passes down the same delivery system as the Working Beam, it provides a good method of checking for integrity of the delivery system. If the aiming beam spot is not present at the distal end of the handpiece, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or not properly working delivery system.

5.5 WARNING
DO NOT PLACE THE LASER OR FIBER CABLE IN THE AUTOCLAVE TO STERILIZE THE SYSTEM. USE COLD DISINFECTING SOLUTIONS TO WIPE DOWN THE FIBER AND THE EXTERIOR OF THE LASER UNIT.

5.6 Systems Procedures

5.6.1 Treatment Area Requirements
The laser should be placed in an area with good ventilation and lighting, The electrical service required is a 110 Volt AC outlet-60Hz. The area where the laser is placed should be free of standing water. Combustible gases should be turned off and all flammable materials or chemicals stored in the area should be removed.

5.6.2 Foot Pedal
It is recommended to use a 9 volt Lithium battery to power the cordless foot pedal. This type of battery has been tested to last for over 100 hours of foot pedal operation. When the battery voltage begins to drop, the foot pedal will begin to beep, signaling that you have approximately 2 hours of operating time left before the battery life is completed. Note: A 9 volt Alkaline battery may be used; however the life expectancy of an Alkaline battery is less than 35 hours of operating time.

5.6.3 Emergency Shutdown Button
Check the Emergency Shutdown Button to see that it has not been depressed. If it has, release it by depressing it slightly as you turn it ¼ turn to the right.

5.6.4 Key Switch
Turn the Key Switch on the front of the laser to the "on" position by turning it approximately ¼ turn to the right (clockwise). The control panel should light up and show the laser is in the Standby Mode.

5.6.5 Setting Parameters *(see Figure 3.2a on page 9)*
Review your power and mode requirements and then depress the mode button to select either Continuous (CW) or pulsed-mode. The mode you have selected will be displayed just below the LED screen and will be designated by a small light in the corner of either of the pulse or CW panel Display.

5.6.6 Power Selection
Press the up or down arrow until you have reached the desired wattage. Beginning with a low of 0.1 Watts, the power increases in increments of 100 mW up to a maximum of 9.0 Watts (CW). By holding the up or down arrow, you can have an un-interrupted increase until you reach your desired power.

5.6.7 Selecting Programs
Press this key to select either manual (M) or one of three user defined programs (P1, P2, P3). Each program will save all of the parameters – working beam, aiming beam and mode of operation. The settings can be changed as desired for any of the program modes. To set the user defined program modes, choose either P1, P2, or P3, set your preferred settings and push the ready button. Upon activating the ready button, the new settings will be retained.

5.6.8 Aiming Beam
The aiming beam can be turned on and off by pressing the aiming beam button on the laser control panel. Press this button to progressively increase the aiming beam intensity from O (off) to full intensity. Press the key once more to cycle back to O. Each bar represents approximately 20% of the aiming beam output. Note: Adjusting the intensity of the aiming beam has no effect on the output power of the primary laser.

5.6.9 Depress the Ready Button
When you depress the ready button, the aiming beam should light after a 2 second delay. Select either CW or pulse mode.

5.6.10 Depress the Foot Pedal
Begin making circular motions as you press the foot pedal and continue to do so while the pedal is pressed.

5.6.11 Remove Your Foot
Remove your foot from the foot pedal and use a clean 2X2 wetted gauze to remove any debris from the handpiece opening.

5.6.12 Place the Laser in Standby Mode
Until you are ready to start another application keep the laser in standby mode.

5.6.13 Self Diagnostic and Monitoring
When the Pilot Diode Laser's microprocessor detects an issue with performance it will immediately notify you by way of an audible beep. There are two different ways in which the Pilot Diode Laser will alert you to any issues:

1. Continuous audible beep when foot pedal is engaged. If you are operating the Pilot Diode Laser with the foot pedal engaged and the Pilot Diode Laser emits a constant audible beep and stops the beep when you release the foot pedal, the microprocessor has determined that the laser power output has fallen below the set level. In this event the Pilot Diode Laser should be turned off and allowed to sit for 5 minutes then turned on again. If the Pilot Diode Laser then performs without beeping, the microprocessor has been able to make operational adjustments to the laser and the unit will perform its functions. If, however, upon restart the unit continues to beep when the foot pedal is engaged, the microprocessor was unable to adjust the unit enough and the unit will need to be sent in for adjustment. (Section 6)

2. Continuous audible beep when the unit is turned on. If you are operating the Pilot Diode Laser and it emits a constant audible beep whether or not the foot pedal is engaged, the microprocessor has determined that the laser has either low power or a general fault has occurred. In this event the Pilot Diode Laser should be turned off and allowed to sit for 5 minutes and turned on again. If the Pilot Diode Laser then performs without beeping, the microprocessor has been able to make operational adjustments to the laser and the unit will perform its functions. If, however, upon restart the unit continues to beep, the microprocessor was unable to adjust the unit enough and the unit will need to be sent in for adjustment.

SECTION 6 – SYSTEM COMPONENTS PREPARATIONS, CARE AND MAINTENANCE

The fiber optic element of a laser is responsible for carrying the light from the diode array to the tissue being treated. Laser fibers are usually made of quartz, sapphire, silica or a combination of those elements. Quartz/silica is the most popular product used in diode lasers. Be advised about the potential hazards when inserting, steeply bending or improperly securing the fiber cable. Radiation exposure may occur in these instances which could be harmful to yourself, your staff and your patient. Special care should be taken not to kink or crush the fiber. As the Aiming Beam passes down the same delivery system as the Working Beam, it provides a good method of checking for integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or not properly working delivery system.

6.1 Laser Maintenance

6.1.1 Laser Chassis Disinfection

The exterior of the laser should be cleaned using a liquid disinfectant similar to Birex™ or Cidex™ . Do not spray the disinfectant directly on the chassis. Apply with a gauze sponge or wipe. Do not use abrasive materials to clean the system. Place a barrier material similar to cellophane over the control panel and LED screen prior to treating the next patient.

6.1.2 Calibration

The Pilot Diode Laser is calibrated at the factory, and requires no user adjustment or periodic calibration once the unit is in use. The laser contains internal calibration programming that continuously monitors and adjusts the working beam power relative to the factory established reference points, ensuring that the laser continuously provides the power output indicated on the display to an accuracy of ± 20%, regardless of how long the unit has been in use. The Pilot Diode Laser uses solid-state circuitry to continuously monitor the power output, and adjusts the power supplied to the laser module to keep the output consistent with the user defined setting. If output levels are more than ± 20% of the set value, the unit is designed to shut down power to the laser, and an audible alarm will sound. If this happens, the unit should be turned off and allowed to sit for 5 minutes and turned on again. If the laser then performs without beeping, the microprocessor has been able to make operational adjustments and the unit will perform its functions. If, upon restart, the unit continues to beep, the unit will need to be sent in for adjustment by the CAO Group Warranty Department. It is suggested that your practice establish an internal calibration verification program for your laser. Verification is recommended a minimum of once per year based on average usage. Verification may be performed by the manufacturer by returning the unit. As an alternative, you may purchase a calibrated hand held power meter approved for use with 810nm devices to check power output. The laser should be set at 1, 3 and 9 Watts with output checked at each level. The output display should be within 20% of the meter reading. If the output display is outside the 20% tolerance, return the unit to the manufacturer for recalibration. There are no methods available for the user to adjust the calibration of the unit and the unit chassis must not be removed by the user for any reason.

6.2 Handpiece Preparation

Prior to installing one of the included handpieces, remove the dust cap that protects the fiber. To remove, just pull the dust cap out from the end of the handpiece stem. The dust cap should be replaced when the laser is not in use or being stored.

6.2.1 Autoclavable

The handpiece sleeve is autoclavable and should be cleaned with warm soapy water, rinsed and bagged after each patient.

6.2.2 Interchanging Handpieces

When interchanging the handpieces from surgical (if included) to therapeutic, and vice-versa, first make sure to remove the fiber tip at the end of the surgical handpiece. You will then simply unscrew the handpiece counterclockwise from the base. Next, pull the handpiece off over the end of the fiber. Then select which handpiece you would like use and slide it on and fasten it to the base. You may then adjust your setting accordingly. Follow these same steps when interchanging any handpiece.

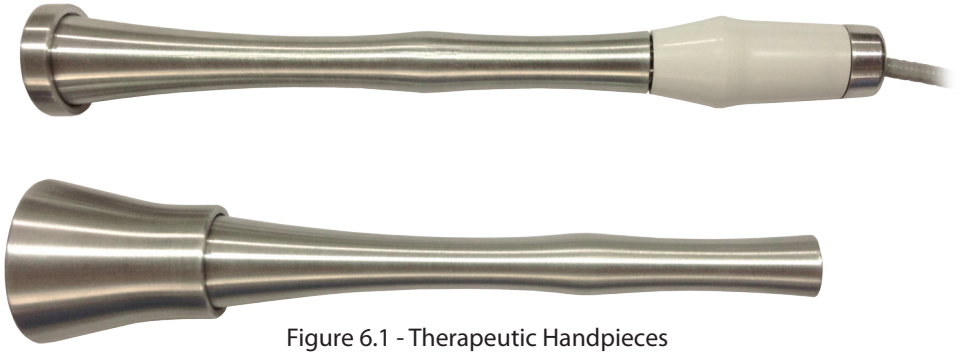


Figure 6.1 - Therapeutic Handpieces

SECTION 7 – LABELS, SIGNS, WARNINGS AND MANUFACTURER'S INFORMATION

7.1 Federal Compliance

The Pilot Diode Laser has been designed to the latest safety standards applicable to medical lasers in the US and Canada, including IEC 60825, IEC 60601-2-22, IEC 60601-1 and the Food and Drug Administration's Laser Performance Standard (21 CFR 1040.10 and 1040.11). The laser has also been certified and tested according to the telecommunications regulations for the US (FCC Part 15), Canada (IC RSS 210) and the European Community (EN 300 328, and EN 301 489). Various labels are included on the laser and the wireless footswitch as evidence of conformity to these requirements. The labels on the unit are required under these standards for safety purposes and should not be removed. Please review all labels prior to using the laser. (SEE Figures 7.0.1 through 7.0.9)

VISIBLE AND INVISIBLE LASER RADIATION. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.
WAVELENGTH:810NM OUTPUT:9 WATTS
WAVELENGTH:650NM OUTPUT: 3mW
CLASS 4 LASER PRODUCT
RAYONNEMENT LASER VISIBLE ET INVISIBLE. EXPOSITION DANGEREUSE DE L'OEIL OU DE LA PEAU AU RAYONNEMENT DIRECT OU DIFFUS
LA LONGUER D'ONDE:810NM
ÉMISSION MAXIMALE: 9 WATTS
LA LONGUER D'ONDE:650NM
ÉMISSION MAXIMALE:3mW
APPAREIL A LASER DE CLASSE 4

Figure 7.0.1 Label required under FDA Laser Notice 50

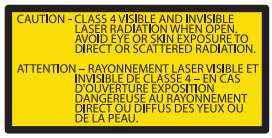

CAUTION - CLASS 4 VISIBLE AND INVISIBLE LASER RADIATION WHEN OPEN. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.
ATTENTION – RAYONNEMENT LASER VISIBLE ET INVISIBLE DE CLASSE 4 – EN CAS D'OUVERTURE EXPOSITION DANGEREUSE AU RAYONNEMENT DIRECT OU DIFFUS DES YEUX OU DE LA PEAU.

Figure 7.0.2 Label required under FDA laser notice 50

Figure 7.0.3 Laser aperture label

PILOT DIODE LASER
POWER INPUT: 100-240V ~ 50-60HZ 1.5A
WORKING BEAM WAVELENGTH: 810±10 NM
810 NM POWER OUTPUT: 9 WATTS
AIMING BEAM WAVELENGTH: 650±30 NM
650 NM POWER OUTPUT: 3 MILLIWATTS
WIRELESS FREQUENCY: 2.4 GHz
FUSE: T2A / 250V
MODEL: 002-00139
MANUF DATE:
SERIAL:
MANUFACTURER:
CAO GROUP INC.
4628 W. SKYHAWK DR.
WEST JORDAN, UT 84084
ASSEMBLED IN USA
FCCID: XSVGC923436
COMPLIES WITH: 21 CFR 1040.10 & 1040.11 EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE 50, DATED JUNE 24, 2007. ALSO CONFORMS TO UL STD 60601-1, IEC STD 60601-2-22; CERTIFIED TO CSA STD C22.2 NO. 601.1, CSA STD C22.2 NO. 601.2.22.
3183713
Intertek
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.
PATENTS PENDING

Figure 7.0.4 Rating label with serial number

DANGER
LASER RADIATION--AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION
9.0W 810nm DIODE LASER
CLASS IV LASER PRODUCT

Figure 7.1

Do Not Reuse

Figure 7.0.5

ATTENTION -- Review Operator's Manual Prior To Use

Figure 7.0.6

CAUTION -- Laser Emitting Device Class 4 Laser

Figure 7.0.7

Type B Applied Parts

Figure 7.0.8

Fuse Compartment -- Use Type 'T' Fuse Rated For 250V, 2A

Figure 7.0.9

7.2 Danger Laser in Use

Each treatment area should have a "laser in use" warning sign posted at the entrance to the treatment area. This signage serves to warn people to not enter the treatment area without proper safety eyewear and protective clothing when the laser is in use. (See Figure 7.1)

7.3 Class 4 Laser Product – (treatment laser) 810nm 9 W

7.4 Aiming Beam Laser – 630 – 660nm, 2 mW

7.5 CAUTION :
Changes or modifications not expressly approved by CAO Group could void the user's authority to operate the equipment.

7.6 CAUTION :
Laser Radiation – Avoid exposure to the eyes or skin from direct or scattered radiation.

7.7 CAUTION :
This product contains no user serviceable components within the chassis. Visible and invisible radiation may be present when the cover is removed.

7.8 CAUTION :
US Federal law restricts the device to sale by or on the order of a licensed professional.

7.9 CAUTION :
Eyewear that protects your eyes from wavelengths other than 810nm do not provide proper protection for use with this laser. Damage to the retina or cornea may be irreparable if exposed to direct, reflected or scattered radiation.

7.10 CAUTION :
Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.

7.11 CAUTION :
Avoid use of oils, gels, or other surface treatments when applying the laser. The handpiece should come in contact with clean, bare skin. Consider trimming or shaving excessive hair if necessary to gain access to the bare skin.

7.12 Nominal Ocular Hazard Distance (NOHD)
The NOHD is the distance beyond which the exposure during normal operation is not to exceed the appropriate Maximum Permissible Exposure (MPE). The NOHD for persons wearing safety glasses is shown in Table 1 below. The Nominal Hazard Zone (NHZ) is the area where the laser source within which exposure levels exceeds the MPE (which is the highest level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eyes or skin). The outer limit of the MHZ is the NOHD. Eye Protection within the NHZ is mandatory.

Source of Radiation	MPE ($mWcm^2$)	Divergence angle (degrees)	NOHD (inches)	
			No Eyewear inches/cm	With Eyewear (OD=4) inches c/m
Fiber optic devices	1.66	13	144/365	1.44/3.65
Reflection from Tissue	1.66	N/A	0.004/0.102	0.00004/0.00102

Assumptions: Maximum Laser Power = 9 Watts Direct viewing angle =0, reflectance viewing angle =20°, reflectance coefficient of tissue = 0.001

Table 1 - Nominal Ocular Hazard Distance (NOHD) for various viewing conditions while wearing eye protection.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. (Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.)

7.13 Warning and Safety Notices:
WARNING: To avoid the risk of electrical shock, this equipment must only be connected to a supply main with protective earth.

7.14 Environmental Protection Disposal Of The Equipment:
This is a medical laser device; dispose of this device and all accessory items in accordance with state, local and federal rules on the disposal of laser equipment.

7.15 Statements Regarding Electromagnetic Compatibility (EMC):

WARNING:

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the performance of the Pilot Diode Laser.
- The use of accessories, transducers and cables other than those specified by CAO Group may result in increased emissions or decreased immunity of the Pilot Diode Laser.
- The Pilot Diode Laser should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Pilot Diode Laser should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Solace Duo Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Solace Duo Laser should assure that it is used in such and environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The Solace Duo Laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2		
Voltage Fluctuations/ Flicker emissions		
The PILOT Laser is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

Guidance and manufacturer's declaration – electromagnetic immunity			
The Solace Duo Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Solace Duo Laser should assure that it is used in such and environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PILOT Laser requires continued operation during power mains interruptions, it is recommended that the PILOT Laser be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Solace Duo Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Solace Duo Laser should assure that it is used in such and environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PILOT Laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3,5/V1]√P d = [3,5/E1]√P 80 MHz to 800 MHz d = [7/E1]√P 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PILOT Laser is used exceeds the applicable RF compliance level above, the PILOT Laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PILOT Laser. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

SECTION 8 – SERVICING

8.0 Limited Warranty Policy:

The Pilot Diode Laser is warranted against defective materials and workmanship for a period of two (2) years and the handpiece and cable assembly for six (6) months from the date of purchase, and will be repaired, at our discretion, if returned prepaid to our factory. This warranty does not cover damage to the Pilot Diode Laser unit or components caused by accident, misuse, or being tampered with. This warranty does not include labor, postage, or delivery charges. This warranty does not apply to the external finish of the console, power cord, or foot pedal. CAO Group reserves the right to make changes in the design or to modify such previously manufactured products. Your Pilot Diode Laser warranty does not become effective unless the registration card is sent to CAO Group in the mail within ten (10) days of the purchase, with all invoice and serial number information completely filled in.

8.0.1 Repairs and Returns

Send repair and returns to CAO Group. Should the laser fail to operate correctly, please call CAO Group Customer Service (1-877-236-4409) to obtain a Return Materials Authorization (RMA) number for shipping purposes. Please insure that the RMA number is clearly marked on the box used to return the laser. Please clearly state the reasons for return.
Send returns to: CAO Group Service Center Attn: Warranty Department 4628 W Skyhawk Dr. West Jordan, UT 84084 USA

CAUTION! Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

CAUTION! Do not attempt to remove the cover from the laser chassis for the purpose of repairing the laser. Serious injury from an electrical shock or laser radiation could occur. Removing the cover on the laser chassis will void the warranty.

8.1 FDA And Laser Standards

Medical Laser Standards

The Pilot Diode Laser has been designed to the latest safety standards applicable to medical lasers in the US and Canada including CAN/CSA c 22.2 #601.1, IEC 60825, IEC 60601-2-22, IEC 60601-1 and the Food and Drug Administration's Laser Performance Standard (21 CFR 1040.10 and 1040.11), US (FCC Part 15) , Canada (IC RSS 210) and the European Community (EN 300 328, and EN 301 489). Various labels are included on the laser and the wireless foot switch as evidence of conformity to these requirements. The labels on the units are required under these standards for safety purposes and should not be removed. Please review all labels prior to using the laser.

Wireless Technology

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation. The wireless footswitch complies with US FCC, Title 47 (47 CFR); Canada, IC-RSS 210 (Radio Standards Specification); and European Community, EN 300 328, EN 60950 and EN 301 489.

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. (Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.)

OSHA and its Provisions
Worker safety is the responsibility of the employer and is regulated by OSHA (Occupational Safety and Health Administration), a division of the U.S. Department of Labor. OSHA has issued no specific standard for safe use of lasers but recognizes ANSI standard Z136.1 as a source for analyzing safety with respect to medical lasers. For more information see OSHA Technical Manual (TED 1-0.15A) Section III, Chapter 6, 1999. CAO Group recommends implementation of a Laser Safety Program for the safety of your patients and office staff in connection with the use of the Pilot Diode Laser.

American National Standards Institute
(ANSI) - Safety Standards ANSI is a non-governmental, non-profit agency that has established guidelines and safety standards for the use of lasers and other electro-optics. The provisions of ANSI Z 136.3 outline standards for lasers used in medicine and the assessment of laser risks. ANSI establishes guidelines for safety eyewear, and classifies all lasers based on their potential for damage to eyes or tissue.

8.2 TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
The unit does not appear to have any power.	The unit is not plugged in.	Make sure the main switch is off. Plug the unit into the wall supply. Turn the main switch and key switch on.
	The main switch is off.	Press the main switch (I) on the back of the unit.
	The key switch is off.	Insert the key and turn the switch to the "On" position.
The fan can be heard, but there is no display.	The emergency switch is engaged.	Rotate the emergency switch cap in the direction shown by the arrows on the cap. If the switch was engaged, the button should pop up.
	The cartridge lock is dislodged.	Push the cartridge lock towards the side of the housing, and make sure it is fully seated against the side of the housing, and the back of the cartridge.
	Remote interlock loop is open.	If a connection is plugged into the Remote Interlock receptacle on the back of the laser, check to make sure the door is closed. If this does not solve the problem, briefly disconnect the remote interlock. If the unit's display illuminates, turn the unit off and do not use the laser until a qualified electrician can inspect the remote interlock switch connections.
No aiming beam is visible.	Aiming beam is set too low.	Press the "Aiming Beam" button to increase the aiming beam setting.
	Dust cap has not been removed.	Remove the dust cap out from the end of the handpiece stem.
The foot pedal does not respond.	The laser is not in "Ready" mode.	Look at the display, and make sure the "Ready" indicator is illuminated. If not, press the READY key.
	There are other wireless devices causing interference.	Turn off the laser's key switch or main switch. Wait 1-2 minutes, then turn the unit on and try again. If this doesn't work, turn off the laser and move the laser and foot pedal to a different location in the room. Try changing the wireless channel.
	There are large metal surfaces between the laser and foot pedal.	Turn off the laser and move the laser and foot pedal to a different location in the room, or remove the metal surface that is between the laser and foot pedal.
	The battery in the foot pedal is low.	Replace the battery with a recommended 9 Volt Lithium battery.
Foot pedal beeps.	Battery is low.	Replace the battery with a recommended 9 Volt Lithium battery.
Display shows "Er" and the laser beeps continuously.	Program malfunction.	Turn off the main switch or key switch immediately. Wait 1-2 minutes, and then turn the unit back on. If the error repeats, turn the unit off and contact the dealer or place of purchase.
Power output indicated does not match the results from a power meter.	Power meter is not appropriate for 810nm measurements.	Make sure the power meter used is rated to measure wavelengths in the 810nm range.

Learn more about the Pilot Diode Laser at www.pilotlasers.com

CAO GROUP, INC.
Easier · Faster · Better™

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